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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|--|-----------------|----------------------|-------------------------------|-----------------|
| 10/712,456 | 11/13/2003 | Lawrence G. Hamann | LA0091 NP | 9300 |
| 23914 | 7590 09/18/2006 | | EXAMINER | |
| LOUIS J. WILLE | | | BALASUBRAMANIAN, VENKATARAMAN | |
| BRISTOL-MYERS SQUIBB COMPANY PATENT DEPARTMENT | | | ART UNIT | PAPER NUMBER |
| P O BOX 4000 | | | 1624 | |
| PRINCETON, NJ 08543-4000 | | | DATE MAILED: 09/18/2006 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief

| Application No. | Applicant(s) | |
|---------------------------------|---------------|--|
| 10/712,456 | HAMANN ET AL. | |
| Examiner | Art Unit | |
| Venkataraman Balasubramanian | 1624 | |

| | Venkataraman Balasubramanian | 1624 | | | |
|--|---|--|--|--|--|
| The MAILING DATE of this communication appe | ars on the cover sheet with the o | correspondence add | ress | | |
| THE REPLY FILED <u>31 August 2006</u> FAILS TO PLACE THIS AI | PPLICATION IN CONDITION FOR | ALLOWANCE. | | | |
| 1. The reply was filed after a final rejection, but prior to or on this application, applicant must timely file one of the follow places the application in condition for allowance; (2) a No a Request for Continued Examination (RCE) in compliance time periods: | ving replies: (1) an amendment, aft tice of Appeal (with appeal fee) in (| fidavit, or other evider compliance with 37 C | nce, which FR 41.31; or (3) | | |
| a) The period for reply expires <u>3</u> months from the mailing date | of the final rejection. | | | | |
| b) The period for reply expires on: (1) the mailing date of this A no event, however, will the statutory period for reply expire to | dvisory Action, or (2) the date set forth ater than SIX MONTHS from the mailin | g date of the final rejecti | on. | | |
| Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f). | | | | | |
| Extensions of time may be obtained under 37 CFR 1.136(a). The date have been filed is the date for purposes of determining the period of ex under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the set forth in (b) above, if checked. Any reply received by the Office later may reduce any earned patent term adjustment. See 37 CFR 1.704(b) | tension and the corresponding amount shortened statutory period for reply orig than three months after the mailing da | of the fee. The appropri inally set in the final Offi | iate extension fee ce action; or (2) as | | |
| <u>NOTICE OF APPEAL</u> 2. | dianas with 27 CER 41 27 must be | filed within two month | an of the date of | | |
| filing the Notice of Appeal (37 CFR 41.37(a)), or any external a Notice of Appeal has been filed, any reply must be filed | nsion thereof (37 CFR 41.37(e)), to | avoid dismissal of th | | | |
| <u>AMENDMENTS</u> | | | | | |
| 3. The proposed amendment(s) filed after a final rejection, | | | ecause | | |
| (a) They raise new issues that would require further co | | TE below); | | | |
| (b) ☐ They raise the issue of new matter (see NOTE belo (c) ☐ They are not deemed to place the application in bet appeal; and/or | • • | ducing or simplifying | the issues for | | |
| (d) They present additional claims without canceling a | corresponding number of finally rej | ected claims. | | | |
| NOTE: (See 37 CFR 1.116 and 41.33(a)). | | | | | |
| The amendments are not in compliance with 37 CFR 1.13 Applicant's reply has overcome the following rejection(s) | | empliant Amendment | (PTOL-324). | | |
| Newly proposed or amended claim(s) would be all non-allowable claim(s). | | timely filed amendme | ent canceling the | | |
| For purposes of appeal, the proposed amendment(s): a) how the new or amended claims would be rejected is pro- | | II be entered and an e | explanation of | | |
| The status of the claim(s) is (or will be) as follows: Claim(s) allowed: | | | | | |
| Claim(s) objected to: <u>1 and 3-7</u> . | | | | | |
| Claim(s) rejected: 8 and 9. | | | | | |
| Claim(s) withdrawn from consideration: AFFIDAVIT OR OTHER EVIDENCE | | | | | |
| 8. ☐ The affidavit or other evidence filed after a final action, bu | t before or on the date of filing a N | otice of Appeal will no | at he entered | | |
| because applicant failed to provide a showing of good and was not earlier presented. See 37 CFR 1.116(e). | d sufficient reasons why the affidat | rit or other evidence is | s necessary and | | |
| The affidavit or other evidence filed after the date of filing entered because the affidavit or other evidence failed to o showing a good and sufficient reasons why it is necessary | vercome all rejections under appe | al and/or appellant fai | ils to provide a | | |
| 10. ☐ The affidavit or other evidence is entered. An explanation | • | | • | | |
| REQUEST FOR RECONSIDERATION/OTHER | | • | | | |
| 11. The request for reconsideration has been considered bu | t does NOT place the application in | n condition for allowar | nce because: | | |
| 12. ☐ Note the attached Information Disclosure Statement(s). 13. ☒ Other: See attached Advisory Action. | (PTO/SB/08) Paper No(s) | | | | |
| | \ / | | , , ^ | | |
| | Vei | Venkataraman Bal Primary Examiner | asubramanian | | |
| | | Art Unit: 1624 | 9114/06 | | |

U.S. Patent and Trademark Office PTOL-303 (Rev. 08-06)

9114/0%

DETAILED ACTION

The applicants' response, which included amendment to claims, filed 8/31/2006 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance for the following reasons.

Rejection of claims 8 and 9 under U.S.C. 112, first paragraph is maintained as applied to fragility an or age related functional decline for reasons of record elaborated in the previous office action

Applicants' amendment to limit these claims to method of treating or delaying the progression of functional decline, besides treating prostate cancer, did not overcome this rejection for reasons of record.

To repeat, as noted in the previous office action, instant claims, as recited, are reach through claims. A reach through claim is a claim drawn to a mechanistic, receptor binding or enzymatic functionality in general format and thereby reach through a scope of invention for which they lack adequate written description and enabling disclosure in the specification.

In the instant case, it appears that, because the instant compounds modulate androgen receptor, it is recited that, based on this modulation of AR, all age related diseases generically embraced in the claim language of claim 8 can be treated with the instant compounds for which there is no adequate written description and enabling disclosure.

Applicants' argument is also clearly indicative of emphasis on the mode of action and then reaching through to treat any or all age related diseases based on the mode of

action. The pages and line numbers pointed out by the application does not lend support for treating all such diseases.

Hence, based on these considerations, the rejection is deemed as proper and is maintained.

Allowable Subject Matter

Claims 1 and 3-7 are objected to, as there appears to be typographical error in Y definition. Note Y=CH fails to meet the valence of the carbon. These claims would be allowable, barring finding of any prior art in a subsequent search if rewritten in corrected form showing proper support for the same and deleting non-elected subject matter.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For

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9/14/2006